REMARKS

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (U.S. Publication No. 2003/0229013) ("Wu") and Toshiyuki et al. (JP Patent Application No. 10-082882) ("Toshiyuki") (identified as JP 11-255807 A in the IDS filed with the application)

Applicant understands the position of the Office to be that the process of the present invention differs from the prior art (applicant believes the Office is referring to Wu) only in that the process of the present invention "incorporates Toshiyuki's Fmoc protected sugar-linked Asp residue." The Office asserts that it would have been obvious at the time of the present invention to incorporate Fmoc protected sugar-linked Asp residue into the "well know" [sic] Merrifield solid phase peptide syntheses to make a glycosylated peptide because Toshiyuki teaches that Fmoc protected sugar-linked Asp residues are compatible with peptide synthesis and because the methodology of solid phase synthesis is so well known that one of ordinary skill in the art would be able to adapt the coupling steps beyond Toshiyuki's teaching to incorporate numerous and different sugar residues beyond those presently claimed.

Applicant respectfully submits that the Office has failed to properly support its rejection.

First, the Office has not shown where each of the steps recited in claims 1-12 of the present application are disclosed in Wu, alone or as modified by Toshiyuki.

Second, obviousness under 35 U.S.C. \$ 1.03(a) consideration of the prior art as a whole. The Office has failed to consider the prior art as a whole. Applicant respectfully submits that when the prior art as a whole relating to the asparagine-linked glycopeptides having preparation of oligosaccharides is considered, the Office has not properly supported a case of prima facie obviousness of the process for preparing a glycopeptide having at least one asparagine-linked recited in the claims of the present oligosaccharide as application.

The present application on pages 3-5 describes that the solid-phase synthesis process developed by Merrifield (referred to by the Office in the 35 U.S.C. § 103(a) rejection) is presently in wide use for the preparation of peptides, including glycopeptides. However, such process has the problem of insufficient amounts of oligosaccharides to be linked with the asparagine residue and the possibility that the trifluoroacetic acid treatment for cutting off the peptide chain from the solid phase will cut off sialic acid from the glycopeptide prepared.

Wu discloses solid phase chemical synthesis but discloses nothing concerning oligosaccharides. Toshiyuki, on the other hand, discloses nothing concerning solid phase chemical synthesis. Example 4 of Toshiyuki, disclosing preparation of a glycopeptide, does not use a solid carrier (resin). Toshiyuki discloses liquid phase chemical synthesis.

When the disparate disclosures of Wu and Toshiyuki are considered in light of the problems in the prior art for preparing glycopeptides in reasonable amounts and of introducing sialic acid or derivatives thereof into oligosaccharides using solid phase synthesis, a person of ordinary skill in the art could not have reasonably predicted that the proposed modification of the solid phase chemical synthesis process of Wu would be successful in preparing acceptable amounts of glycopeptides having at least one asparagine-linked oligosaccharide.

Regarding the issue of obviousness, it is noted that the IPER (International Preliminary Examination Report) of the present application found that the process set forth in claims 1-12 is unique in the discovery that sugar chain asparagine can be used in the solid phase synthesis of a peptide without protecting hydroxyl groups. Applicant submits that the reasoning of the IPER is

applicable to the propriety of the 35 U.S.C. § 103(a) rejection in the present Action.

For the above reasons, removal of the 35 U.S.C. 103(a) rejection of the claims is believed to be in order and is respectfully requested.

As requested by the Office on page 5 of the Action, the following copending applications set forth similar subject matter to the present application:

10/540,503;

10/540,619;

10/540,623; and

10/544,212.

A copy of the claims of each of these applications is submitted herewith.

The foregoing is believed to be a complete and proper response to the Office Action dated June 7, 2007, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicant hereby petitions for an appropriate extension of

PATENT APPLN. NO. 10/519,983 RESPONSE UNDER 37 C.F.R. §1.111

time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

KUBOVCIK & KUBOVCIK

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Atty. Case No. TAM-051 The Farragut Building Suite 710 900 17th Street, N.W. Washington, D.C. 20006 Tel: (202) 887-9023 (202) 887-9093 Fax: RJK/JBF

Claims of application Serial Nos. 10/540,503; Attachments:

10/540,619; 10/540,623; and 10/544,212

ing biotinated oligosaccharide collected by washing. Subsequently, 10 ml of heads having the biotinated asparaginelinked oligosaccharide fixed thereto and 30 ml of distilled water were packed in the form of a slurry into an open chromatographic glass column (20 mm in diameter, 300 mm 5 in length) to produce an affinity column.

INDUSTRIAL APPLICABILITY

The present invention provides 3-branched asparagine- 10 FITC group. linked oligosaccharide derivatives, as isolated and useful in the field of developing pharmaceutical products, in Jarge quantities with much greater ease than the prior art. In addition to these derivatives, the invention further provides isolated 3-branched asparagine-linked oligosaccharides and 15 3-branched oligosaccharides in large quantities with much greater ease than conventionally.

Utilizing the specificity of biotin-avidin bond, the invention further provides an oligosaccharide microchip easily on an avidinated microplate, whereby protens can be clarified which have ability to bond to a specific oligosaccharide.

In order to isolate and purify a specific protein, a specific biotinated oligosaccharide is bonded and fixed to an avidinated affinity column, and a mixture containing a protein 25 having ability to specifically bond to the biotinated oligosaccharide is passed through the column, whereby the desired protein only can be isolated.

The FTTC-bonded asparagine-linked oligosaccharide obtained by the invention is useful for the research on 30 acceptors of saccharides in the living hody tissues and for the research on the sugar bond specificity of lectin.

The invention claimed is:

1. A 3-branched asparagine-linked oligosaccharide derivative of the formula (1) wherein the nitrogen of amino 35 group of asparagine is modified with a lipophilic protective group, biotin group or FITC group

continued

wherein Q is a lipophilic protective group, biotin group or

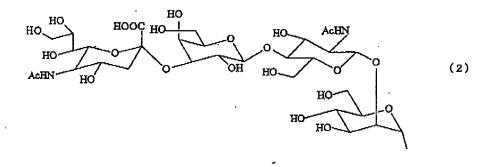
- 2. A 3-branched asparagine-linked oligosaccharide derivative according to claim 1 which contains at least one fucose linked to an N-acetylglucosamine on the nonreducing terminal side of the 3-branched asparagine-linked oligosaccharide of the derivative.
- 3. A 3-branched asparagine-linked oligosaecharide derivative according to claim 1 or 2 wherein the lipophilic protective group is an Fmoc group.
- 4. A process for preparing a 3-branched asparagine-linked merely by reacting a plurality of biotinated oligosaccharides 20 oligosaccharide derivative having a lipophilic protective group introduced thereinto, the process being characterized in that the process includes:
 - (a) the step of introducing a lipophilic protective group into one or at least two 3-branched asparagine-linked oligosaccharides as contained in a mixture thereof to obtain a 3-branched aspuragine-linked oligosaccharide derivative mixture, and
 - (b) the step of subjecting to chromatography the 3-branched asparagine-linked oligosaccharide derivative mixture or a mixture obtained by hydrolyzing the 3-branched asparagine-linked oligosaccharide derivative or derivatives contained in the 3-branched asparagine-linked oligosaccharide derivative mixture to separate the derivative or derivatives.
 - 5. A process for preparing a 3-branched asparagine-linked oligosaecharide derivative modified with a biotin group characterized by biotinating a 3-branched asparagine-linked oligosaccharide.
 - A process for preparing a 3-branched asparagine-linked oligosaccharide derivative modified with an FITC group characterized by bonding FITC to a 3-branched asparaginelinked oligosaccharide.
 - 7. A process for preparing a 3-branched asparagine-linked oligosaccharide characterized by removing a lipophilic protective group, biotin group or FITC group from a 3-branched asparagine-linked oligosaccharide derivative.
 - 8. A microplate having immobilized thereto a biotinated 3-branched usparagine-linked oligosaccharide of claim 1 or
 - 9. An affinity column having immobilized thereto a biotinated 3-branched asparagine-linked oligosaccharide of claim 1 or 2.

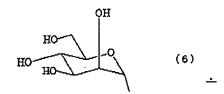
U.S. National Stage of PCT/JP2003/016682 PRELIMINARY AMENDMENT

IN THE CLAIMS:

1. (currently amended) An asparagine-linked oligosaccharide of the formula (1) given below having undeca- to tri-saccharides

wherein R^1 and R^2 are each a hydrogen atom or a group of the formulae (2) to (6) and may be the same or different, and Q is a biotin group or FITC group[[.]]





- 2. (currently amended) An asparagine-linked $(\alpha 2,3)$ or $(\alpha 2,6)$ oligosaccharide derivative having undeca- to hepta-saccharides and represented by the formula (1) wherein one of R^1 and R^2 is always a group of the formula (2) or (3), wherein formula (1), formula (2) and formula (3) are as defined in claim 1.
- 3. (currently amended) An asparagine-linked $(\alpha 2,3)$ $(\alpha 2,6)$ oligosaccharide derivative having undecasaccharide and represented by the formula (1) wherein R^1 is a group of the formula (2), and R^2 is a group of the formula (3), wherein formula (1), formula (2) and formula (3) are as defined in claim 1.
- 4. (currently amended) An asparagine-linked ($\alpha 2,3$) ($\alpha 2,6$) oligosaccharide derivative having undecasaccharide and represented by the formula (1) wherein R¹ is a group of the formula (3), and R² is a group of the formula (2), wherein formula (1), formula (2) and formula (3) are as defined in claim 1.

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- 5. (original) An asparagine-linked oligosaccharide derivative containing at least one fucose in N-acetylglucosamine on the nonreducing terminal side of an asparagine-linked oligosaccharide wherein the amino group of asparagine is modified with a biotin group or FITC group.
- 6. (currently amended) An asparagine-linked oligosaccharide derivative containing fucose and according to claim 5 wherein the asparagine-linked oligosaccharide having a biotin group or FITC group modifying the amino group of asparagine is an asparagine-linked oligosaccharide derivative of the formula (1) having undecato tri-saccharides

wherein R¹ and R² are each a hydrogen atom or a group of the formulae (2) to (6) and may be the same or different, and O is a biotin group or FITC group

U.S. National Stage of PCT/JP2003/016682 PRELIMINARY AMENDMENT

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7. (currently amended) An asparagine-linked oligosaccharide derivative containing fucose and according to claim 5 wherein the asparagine-linked oligosaccharide having a biotin group or FITC group modifying the amino group of asparagine is an asparagine-linked ($\alpha 2,3$) ($\alpha 2,6$) oligosaccharide derivative according to claim 3 and having undecasaccharide and represented by the formula (1).

wherein R^1 is a group of the formula (2), and R^2 is a group of the formula (3) and O is a biotin group or FITC group

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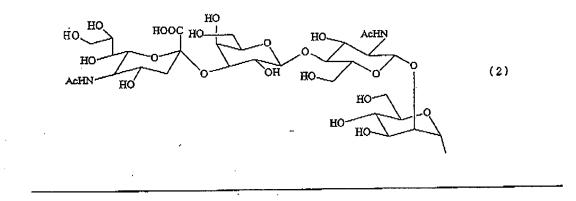
8. (currently amended) An asparagine-linked oligosaccharide derivative containing fucose and according to claim 5 wherein the asparagine-linked oligosaccharide having a biotin group or FITC group modifying the amino group of asparagine is an asparagine-linked ($\alpha 2,3$) ($\alpha 2,6$) oligosaccharide derivative according to claim 4 and having undecasaccharide and represented by the formula (1)

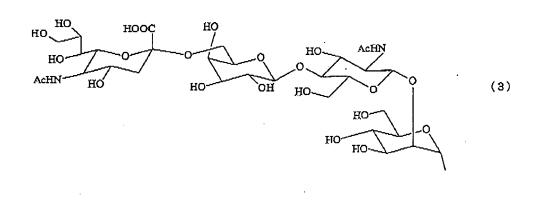
wherein R^1 is a group of the formula (3), and R^2 is a group of the formula (2) and 0 is a biotin group or FITC group

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9. (currently amended) An asparagine-linked oligosaccharide derivative containing fucose and according to claim 5 wherein the asparagine-linked oligosaccharide having a biotin group or FITC group modifying the amino group of asparagine is an asparagine-linked $\alpha 2,3$ oligosaccharide derivative having undecato hexasaccharides and represented by the formula (1)

wherein R^1 and R^2 are each a hydrogen atom, a group of the formula (2) or a group of the formulae (4) to (6), and one of R^1 and R^2 is always a group of the formula (2) or (4), and 0 is a biotin group or FITC group





10. (currently amended) An asparagine-linked oligosaccharide derivative containing fucose and according to claim 5 wherein the asparagine-linked oligosaccharide having a biotin group or FITC

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group modifying the amino group of asparagine is an asparagine-linked $\alpha 2,6$ oligosaccharide derivative having undeca- to hexa-saccharides and represented by the formula (1)

wherein R^1 and R^2 are each a hydrogen atom, a group of the formula (3) or a group of the formulae (4) to (6), and one of R^1 and R^2 is always a group of the formula (3) or (4), and O is a biotin group or FITC group

11. (currently amended) A process for preparing a biotinated asparagine-linked oligosaccharide characterized in that an asparagine-linked oligosaccharide of the formula (7) having undeca-

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to tri-saccharides is biotinated

wherein R1 and R2 are as defined above defined in claim 1.

- 12. (currently amended) A process for preparing a FITC-bonded asparagine-linked oligosaccharide characterized in that an asparagine-linked oligosaccharide of the formula (7) having undecato tri-saccharides is fluorescein isothiocyanated (FITC-bonded), wherein formula (7) is as defined in claim 11.
- 13. (currently amended) A microplate having immobilized thereto a biotinated asparagine-linked oligosaccharide according to claims 1 to 10 claim 1.
- 14. (currently amended) An affinity column having immobilized thereto a biotinated asparagine-linked oligosaccharide according to claims 1 to 16 claim 1.

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PATENT APPLN. NO. 10/540,503 RESPONSE UNDER 37 C.F.R. \$1.111 PATENT NON-FINAL

IN THE CLAIMS:

1 - 8. (canceled)

9. (currently amended) A process for preparing an asparagine-linked $\alpha 2,3$ -monosialooligosaccharide derivative having nonasaccharide and represented by the formula (14) given below, the process being characterized by hydrolyzing an asparagine-linked monosialooligosaccharide derivative represented by the formula (13) using a galactosidase

wherein one of R1 and R2 is a group represented by the formula (2),

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wherein R, R' and R" are in the following combinations

(a) R=F, R'=OH, R''=OH,

(b) R=OH, R'=F, R''=OH,

(c) R=OH, R'=OH, R''=F, and

(d) R=OH, R'=OH, R"=OH,

and the other thereof is a group represented by the formula (4),

the process being characterized by hydrolyzing an asparagine-linked monosialooligosaccharide derivative represented by the formula (13) using a galactosidase

wherein one of R^1 and R^2 is a group represented by the formula (2), and the other is represented by formula (3).

wherein one of R^{\pm} and R^{\pm} is a group represented by the formula (2), and the other thereof is a group represented by the formula (4), wherein formula (2) and formula (4) are as defined in claim 1.

10. (currently amended) A process for preparing an asparagine-linked $\alpha 2,3$ -monosialooligosaccharide derivative having octasaccharide and represented by the formula (15) given below, the process being characterized by hydrolyzing an asparagine-linked monosialooligosaccharide derivative represented by the formula (14) using an N-acetylglucosaminidase

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wherein one of R^1 and R^2 is a group represented by the formula (2),

wherein R, R' and R" are in the following combinations

- (a) R=F, R'=OH, R"=OH,
- (b) R=OH, R'=F, R''=OH,
- (c) R=OH, R'=OH, R''=F, and
- (d) R=OH, R'=OH, R"=OH,

and the other thereof is a group represented by the formula (5),

the process being characterized by hydrolyzing an asparagine-linked monosialooligosaccharide derivative represented by the formula (14) using an N-acetylglucosaminidase

wherein one of R^1 and R^2 is a group represented by the formula (2). and the other thereof is a group represented by the formula (4),

wherein one of R^{\pm} and R^{2} is a group represented by the formula (2), and the other thereof is a group represented by the formula (5), wherein formula (2) and formula (5) are as defined in claim 1.

11. (currently amended) A process for preparing an asparagine-linked $\alpha 2$, 3-monosialooligosaccharide derivative having heptasaccharide and represented by the formula (16) given below, the process being characterized by hydrolyzing an asparagine linked monosialooligosaccharide derivative represented by the formula (15) using a mannosidase

wherein one of R^1 and R^2 is a group represented by the formula (2),

wherein R. R' and R" are in the following combinations

(a) R=F, R'=OH, R''=OH,

(b) R=OH, R'=F, R"=OH,

(c) R=OH, R'=OH, R"=F, and

(d) R=OH, R'=OH, R"=OH,

and the other thereof is a hydrogen atom;

the process being characterized by hydrolyzing an asparagine-linked monosialooligosaccharide derivative represented by the formula (15) using a mannosidase

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wherein one of R^1 and R^2 is a group represented by the formula (2) and the other thereof is a group represented by formula (5),

wherein one of R^t and R^z is a group represented by the formula (2) as defined in claim 1, and the other thereof is a hydrogen atom.

12 - 13. (canceled)

14. (currently amended) A process for preparing an asparagine-linked o2.6-monosialooligosaccharide derivative having nonasaccharide and represented by the formula (19) given below, the process being characterized by hydrolyzing an asparagine-linked monosialooligosaccharide derivative represented by the formula (18) using a galactosidase

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wherein one of R^x and R^y is a group represented by the formula (7)

wherein R, R' and R" are in the following combinations

- (a) R=F, R'=OH, R''=OH,
- (b) R=OH, R'=F, R''=OH, and
- (c) R=OH, R'=OH, R''=F,

and the other thereof is a group represented by the formula (4)

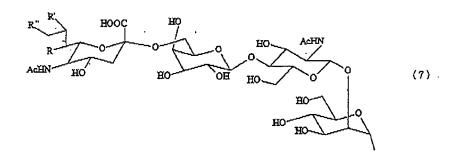
the process being characterized by hydrolyzing an asparagine-linked monosialooligosaccharide derivative represented by the formula (18) using a galactosidase

wherein one of R^x and R^y is a group represented by the formula (7) and the other thereof is a group represented by the formula (3)

15. (currently amended) A process for preparing an asparagine-linked $\alpha 2$, 6-monosialooligosaccharide derivative having octasaccharide and represented by the formula (20) given below, the process being characterized by hydrolyzing an asparagine-linked monosialooligosaccharide derivative represented by the formula (19) using an N-acetylglucosaminidase

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wherein one of R^{κ} and R^{γ} is a group represented by the formula (7)



wherein R, R' and R" are in the following combinations

- (a) R=F, R'=OH, R"=OH,
- (b) R=OH, R'=F, R"=OH, and
- (c) R=OH, R'=OH, R''=F,

and the other thereof is a group represented by the formula (5)

the process being characterized by hydrolvzing an asparagine-linked monosialooligosaccharide derivative represented by the formula (19) using an N-acetylglucosaminidase

wherein one of R^x and R^y is a group represented by the formula (7) and the other thereof is a group represented by the formula (4)

16. (currently amended) A process for preparing an asparagine-linked $\alpha 2$, 6-monosial coligos accharide derivative having heptasaccharide and represented by the formula (21) given below, the process being characterized by hydrolyzing an asparagine-linked

monosialooligosaccharide derivative represented by the formula (20) using a mannosidase

wherein one of R^x and R^y is a group represented by the formula (7) as defined in claim 2, and the other thereof is a hydrogen atom

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wherein R, R' and R" are in the following combinations

(a) R=F, R'=OH, R''=OH,

(b) R=OH, R'=F, R"=OH, and

(c) R=OH, R'=OH, R"=F,

and the other thereof is a hydrogen atom,

the process being characterized by hydrolyzing an asparagine-linked monosialooligosaccharide derivative represented by the formula (20) using a mannosidase

wherein one of R^X and R^Y is a group represented by the formula (7) and the other thereof is a group represented by the formula (5)

17 - 20. (canceled)

21. (currently amended) An asparagine-linked ($\alpha 2,3$) ($\alpha 2,6$)-oligosaccharide derivative having undecasaccharides containing fluorine and represented by the formula (22) given below

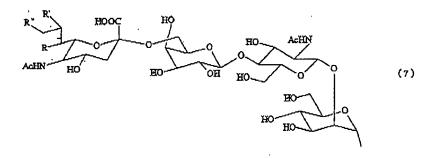
(22)

wherein R^1 is a group represented by the formula (2) as defined in claim 1,

wherein R, R' and R" are in the following combinations

- (a) R=F, R'=OH, R"=OH,
- (b) R=OH, R'=F, R''=OH,
- (c) R=OH, R'=OH, R"=F, and
- (d) R=OH, R'=OH, R''=OH,

and R^y is a group represented by the formula (7) below



wherein R, R' and R" are in the following combinations

- (a) R=F, R'=OH, R"=OH,
- (b) R=OH, R'=F, R''=OH, and
- (c) R=OH, R'=OH, R"=F.
- 22. (currently amended) An asparagine-linked (α 2,3) (α 2,6)-oligosaccharide derivative having undecasaccharides containing fluorine and represented by the formula (23) given below

(23)

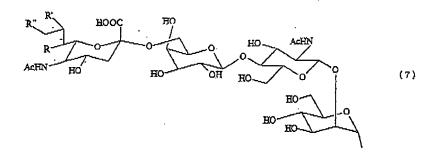
wherein R^2 is a group represented by the formula (2) as defined in claim 1,

wherein R, R' and R" are in the following combinations

- (a) R=F, R'=OH, R"=OH,
- (b) R=OH, R'=F, R''=OH,
- (c) R=OH, R'=OH, R''=F, and
- (d) R=OH, R'=OH, R"=OH

and R^* is a group represented by the formula (7) below[[.]]

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wherein R, R' and R" are in the following combinations

- (a) R=F, R'=OH, R''=OH,
- (b) R=OH, R'=F, R"=OH, and
- (c) R=OH, R'=OH, R"=F.

23 - 28. (canceled)

U.S. National Stage of PCT/JP2004/001048
PRELIMINARY AMENDMENT

IN THE CLAIMS:

- 1. (currently amended) A process for preparing asparaginelinked oligosaccharide derivatives including the steps of: (a) treating a delipidated egg yolk with a protease to obtain a mixture of peptide-linked oligosaccharides, (b) treating the mixture of peptide-linked oligosaccharides with a peptidase to obtain a mixture of asparagine-linked oligosaccharides, (c) introducing a asparagine-linked the lipophilic protective group into oligosaccharides in the mixture to obtain a mixture of asparaginelinked oligosaccharide derivatives, and (d) subjecting the mixture of asparagine-linked oligosaccharide derivatives to a fractionating chromatography using a reverse phase column to separate the mixture into individual asparagine-linked oligosaccharide derivatives.
- 2. (original) A process for preparing asparagine-linked oligosaccharide derivatives as defined in claim 1 wherein the delipidated egg yolk is obtained by delipidating an avian egg yolk with an organic solvent.
- 3. (original) A process for preparing asparagine-linked oligosaccharide derivatives as defined in claim 1 wherein the asparagine-linked oligosaccharide derivatives are asparagine-linked

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undeca- to penta-saccharide derivatives.

- 4. (original) A process for preparing asparagine-linked oligosaccharide derivatives as defined in claim 3 wherein the asparagine-linked oligosaccharide derivatives are asparagine-linked undeca- to hepta-saccharide derivatives.
- 5. (original) A process for preparing asparagine-linked oligosaccharide derivatives as defined in claim 4 wherein the asparagine-linked oligosaccharide derivatives are asparagine-linked undeca- to nona-saccharide derivatives.
- 6. (original) A process for preparing asparagine-linked oligosaccharide derivatives as defined in claim 5 wherein the asparagine-linked oligosaccharide derivatives are asparagine-linked undecasaccharide derivatives.
- 7. (currently amended) A process for preparing sparagine—linked asparagine—linked oligosaccharide derivatives as defined in claim 1 wherein the lipophilic protective group is a carbonate—containing group or acyl group.

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- 8. (currently amended) A process for preparing sparaginelinked asparagine-linked oligosaccharide derivatives as defined in claim 7 wherein the lipophilic protective group is a carbonatecontaining group.
- 9. (currently amended) A process for preparing sparaginelinked asparagine-linked oligosaccharide derivatives as defined in claim 1 wherein the lipophilic protective group is Fmoc group or Boc group.
- 10. (currently amended) A process for preparing sparagine—linked asparagine—linked oligosaccharide derivatives as defined in claim 9 wherein the lipophilic protective group is Fmoc group.
- 11. (currently amended) A process for preparing sparagine—linked asparagine—linked oligosaccharide derivatives as defined in claim 1 wherein the asparagine—linked oligosaccharides contained in the mixture of asparagine—linked oligosaccharides obtained by the step (b) are hydrolyzed before the subsequent step to cut off some sugar moieties.
- 12. (currently amended) A process for preparing sparagine

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linked asparagine-linked oligosaccharide derivatives as defined in claim I wherein the asparagine-linked oligosaccharide derivatives contained in the mixture of asparagine-linked oligosaccharide derivatives obtained by the step (c) are hydrolyzed before the subsequent step to cut off some sugar moieties.